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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,206	01/02/2002	Vishwanath R. Lingappa	UCSF.002.01US	1150

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/02/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/040,206	LINGAPPA ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14 and 51-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14 and 51-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of group IV (claim12-14) in Paper No. 15 is acknowledged. Applicants have added claims 51-53 by amendment in Paper No. 15. Therefore, claims 12-14 and 51-53 are currently under consideration in the instant office action.

Priority

This application is a continuation-in-part, as not all the claims are supported by the parent application, the effective filing date is the filing date of the child CIP. Any prior art disclosing the invention or an obvious variant thereof having a critical reference date more than 1 year prior to the filing date of the child will bar the issuance of a patent under 35 U.S.C. 102(b). *Paperless Accounting v. Bay Area Rapid Transit System*, 804 F.2d 659, 665, 231 USPQ 649, 653 (Fed. Cir. 1986).

In this instance the prior application did not provide any information regarding the sequence of the 68 kD protein found in wheat germ extract or the sequence of the human analog of the wheat germ derived protein. The prior application alos does not diclose an Hp69 knockout mouse. Therefore, claims requiring this information will not be given priority back to the provisional application filed February 17, 1997 and will only be granted the filing date of the instant application January 2, 2002.

Specification

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification.

The disclosure is objected to because of the following informalities: Example 12 is found on page 42 and on page 45, it appears that the example on page 45 should be number 13.

Appropriate correction is required.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper Filed March 29 2002, is attached to the instant Office Action.

Drawings

The petition to accept color drawings filed January 2, 2002 has been **granted**. Applicants have paid the requisite fee and provided the instruction for the amendment to the specification as well as the requisite number of the color drawings.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-14 and 51-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "conformer" renders the claims indefinite because

the ordinary artisan would not know what is meant by this term. Does "conformer" refer to the immature capsid in association with HP68 or does conformer refer to a mutant of HP68. The phrase "conformer" renders the claims indefinite because the specification doe not provide a some standard of measuring the degree intended by the term, thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(f).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant invention is drawn to a method of making monoclonal antibodies, these antibodies are to the chaperone protein involved in the capsid assembly but not the conformer that does not bind gag. The specification has disclosed the production of polyclonal antibodies to wheat germ derived and human derived C-terminal HP68 peptide sequences. The method (claim 12) requires the use of a knockout mouse to produce these antibodies. Neither the specification nor the prior art has provided any teaching regarding such a knockout animal. The specification also has not disclosed any monoclonal antibodies.

Creating new, genetically engineered animal research models involves two transgenic techniques. (1) the classical pronuclear microinjection: introduction of foreign DNA into

embryonic pronuclei resulting in random integration and (2) expression and embryonic stem (ES) cell-mediated gene targeting: introduction of genetically modified ES cells into recipient embryos resulting in the ablation (knockout) or modification of a specific genetic expression (Taconic Newsletter, March 1996, Vol. 1, No. 2, page 4). All transgenic models, whether targeted or untargeted, still may present unpredictable expression patterns due to incomplete knockout of the targeted gene, redundancy within the genome or unanticipated genetic interactions, such as down-regulation of other genes. (Taconic Newsletter, March 1996, Vol. 1, No. 2, page 4).

The claims encompass a genus of compounds (monoclonal antibodies) defined only by their function wherein the relationship between the structural features of members of the genus and said function have not been defined. In the absence of such a relationship either disclosed in the as filed application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound would fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity.

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all

of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was Already for patenting" such as by the use of drawings or structural chemical formulas that show that the invention was complete, or describing distinguishing identifying characteristics sufficient to show that the applicant was in Possession of the claimed invention.

Claimed invention is drawn to an antibody identified by the method of claim 12. However, no structural or specific functional characteristics of such an antibody is provided, nor is there any indication that the artisan actually implemented the method of claim 12 so as to identify any monoclonal antibodies. This situation is analogous to that of *Regents of the University of California v Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention. The claim fails to comply with the written description requirement.

Claims 12-14 and 51-53 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant invention is drawn to a method of making monoclonal antibodies, these antibodies are to the chaperone protein involved in the capsid assembly but not the conformer that does not bind gag. The specification has indicated the production of polyclonal antibodies to wheat germ derived and human derived C-terminal HP68 peptide sequences. The method (claim

12) requires the use of a knockout mouse to produce these antibodies. Neither the specification not the prior art has provided any teaching regarding such a knockout animal. The specification also has not disclosed any monoclonal antibodies.

Creating new, genetically engineered animal research models involves two transgenic techniques. (1) the classical pronuclear microinjection: introduction of foreign DNA into embryonic pronuclei resulting in random integration and (2) expression and embryonic stem (ES) cell-mediated gene targeting: introduction of genetically modified ES cells into recipient embryos resulting in the ablation (knockout) or modification of a specific genetic expression (Taconic Newsletter, March 1996, Vol. 1, No. 2, page 4). All transgenic models, whether targeted or untargeted, still may present unpredictable expression patterns due to incomplete knockout of the targeted gene, redundancy within the genome or unanticipated genetic interactions, such as down-regulation of other genes. (Taconic Newsletter, March 1996, Vol. 1, No. 2, page 4). Indicating that until an animal has actually been created there is a high degree of uncertainty.

To comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must enable one skilled in the art to make and use the claimed invention without undue experimentation. The claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the

claims. Such an analysis does not need to specifically enumerate (points 1-8) but only needs to have a select few of the factors present discussed in a rejection.

The instant fact pattern fails to disclose any particular structure for the claimed monoclonal antibody that requires the use of a knockout animal to create. The specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to have prepared the claimed antibody without undue experimentation. Furthermore an assay for finding a product is not equivalent to a positive recitation of how to make such a product. This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112 first paragraph.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James C. Housel 6/30/03

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600